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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,038	07/17/2002	Harald Bruessow	112843-042	9705
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BELL, BOYD & LLOYD LLP P.O. Box 1135 CHICAGO, IL 60690			EXAMINER CHOWDHURY, IQBAL HOSSAIN	
			ART UNIT 1652	PAPER NUMBER
			NOTIFICATION DATE 12/03/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@BELLBOYD.COM

Office Action Summary

Application No.

10/070,038

Applicant(s)

BRUESSOW ET AL.

Examiner

Iqbal H. Chowdhury, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7, 9, 10, 18-31 and 34-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 7, 9, 10, 18, 20-22, 24-25 and 34-41 is/are rejected.
- 7) ☒ Claim(s) 3, 4, 19, 23, 26 and 28-31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Application Status

In response to a previous Office action, a non-final action (mailed on 2/12/2007), Applicants filed a response and amendment received on July 2, 2007, amending claims 1, 3-4, 7, 9-10, 19, 2123-24, and 26-28, canceling claims 5-6, 8, 11-17, and 32-33, and adding new claims 34-41 is acknowledged.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/2/2007 has been entered.

Claims 1-4, 7, 9-10, 18-31 and 34-41 are currently pending and under consideration in the instant Office action.

Claims 1-4, 7, 9-10, 18-31 and 34-41 will be examined herein.

Applicants' arguments filed on July 2, 2007, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

New-Claim Objections

Claim 4 is objected to as in the recitation "bacterial insertional sequence (IS) S1", which should be "bacterial insertional sequence (ISS1)". Appropriate correction is required.

Claims 7, 27 and 28 are objected to in the recitation "ORF_1560", which should be "ORF

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1560". Appropriate correction is required.

Claim 28 is objected to in the recitation "ORF_90", which should be "ORF 90".

Appropriate correction is required.

Claim 9 is objected to in the recitation "chosen". Examiner suggests the use more appropriate term "selected".

New-Claim Rejections - 35 U.S.C. § 112(2nd)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 2, 18, 22 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2, 18, 22 and 29 are indefinite and confusing because bacterial strains Sf11 and Sf11c16 appear from the specification to be the strains to be modified not the modified strain. Yet, the claim language would suggest that these strains are the modified bacteria.

Maintained-Claim Rejections - 35 USC § 112 (Deposit requirement)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previous rejection of Claim 2 under 35 U.S.C. 112, first paragraph is maintained and claims 18, 22, 25, and 29 are included in this rejection, as failing to comply with the enablement

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requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants argue that Sfi1 strain is known and publicly available and Sfic16 is a lysogenic derivative of Sfi1. This is not persuasive because applicants are using a novel microorganism Sfic16 comprising a modified gene due to insertion DNA material, which may be derived from Sfi1, however, the specification does not disclose how the modified strain Sfic16 was made from parent strain Sfi1 and a skilled artisan would be unable to make exactly a Sfic16 strain as applicants claim from Sfi1. Although, Foley et al. disclose the Sfi1 strain, Foley et al. do not disclose how they obtained said Sfi1 strain. As such Foley et al. is insufficient to show that the sfi1 strain is publicly available. Since the microorganisms are essential to the claimed invention, they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public and a skilled artisan would be unable to obtain and practice the claimed invention. The recited microorganism has not been shown to be publicly known and freely available. The enablement requirements of 35 § U.S.C. 112 may be satisfied by a deposit of the microorganisms. The specification does not disclose a repeatable process to obtain the microorganisms and it is not apparent if the microorganisms are readily available to the public. Accordingly, it is deemed that a deposit of these microorganisms should have been made in accordance with 37 CFR 1.801-1.809.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be available to the public under the conditions specified in 37 CFR 1.808, would satisfy the deposit

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requirement made herein.

If the deposit is not made under the Budapest treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance or compliance by an affidavit or declaration or by a statement by an attorney of record over his or her signature and registration number, showing that:

1. during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
2. upon granting of the patent the strain will be available to the public under the conditions specified in 37 CFR 1.808;
3. the deposit will be maintained in a public repository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
4. the deposit will be replaced if it should ever become unavailable.

Therefore, the rejection is maintained.

New-Claim Rejections - 35 U.S.C. § 112(1st)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 7, 9-10 and 18, 20-22, 24-25, 27, 29, and 34-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are

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directed to a modified of *S. thermophilus* bacterium due to the modification of said bacterial chromosome, which is resistant to attack by bacteriophages due to the insertion of a DNA fragments into the bacterial chromosome or mutation in the prophage genome.

The specification does not contain any disclosure of the structure of all the modifications of a *S. thermophilus* bacterial chromosome or prophage coding region resulting in resistance to bacteriophage infection. The genus of mutant *S. thermophilus* bacterium, which is resistant to attack by bacteriophages, is a large variable genus with the potentiality of having mutations at many different sites of the chromosome, which disrupt the expression of many different proteins and thus have many different effects. The specification does not disclose adequate structure of the modifications of the *S. thermophilus* bacterial chromosome or prophage genome, which resulted in the generation of a modified strain, which is resistant to attack by bacteriophage. The specification fails to describe sufficient information to put one of skill in the art in possession of the claimed invention. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1-2, 7, 9-10, 18, 20-22, 24-25, 27, 34, and 35-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a modified *S. thermophilus* strain Sfi1 and Sfi16, wherein said bacterium is modified by mutation of ORF 90 leading to disruption in expression of the chorismate mutase chain A gene, or a deletion in the

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prophage genome of Sfi21 in ORF1560 which disrupts the expression of said prophage, and starter culture and milk products thereof, does not reasonably provide enablement for any modification of a S. thermophilus strains, wherein said strain comprises any modification to its genomic DNA at any position at any gene leading to disruption in expression of the chorismate mutase chain A gene or any modification of prophage Sfi21 genome at any position or at any gene and starter culture and milk products thereof comprising said bacterial strain. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-2, 7, 9-10, 18, 20-22, 24-25, 27, 34, and 35-41 are so broad as to encompass a modified strain of S. thermophilus bacterium, wherein said strain comprises any modification of its genomic DNA by any means in any ORF or at any gene resulting in disruption of expression of chorismate mutase gene in said bacterium (claims 1-2, 7, 9-10, 18, 20-22, 24, 25, 35-41) or any modification in the in the prophage genome (claims 34-41) broadly encompassed by the claims. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to any modified S. thermophilus bacterium due to any modification of bacterial chromosome (claims 1-2, 7, 9-10, 18, 20-22, 24, 25, 35-41) or any modification in the prophage genome (claims 34-41) broadly encompassed by the claims. While methods of preparing a bacterial strain by mutating prophage genome and the bacterial chromosome in S. thermophilus bacterium in vitro are well known in the art, mutating bacterial chromosome or prophage genome in the bacterial stain so as to produce a strain resistant to any phage infection is not routine. Knowledge of two modifications of S. thermophilus bacterial chromosome or one modification in prophage genome, which is resistant to attack by a specific bacteriophage in

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the said bacterium are unlikely to be provide any guidance for producing other types of mutants of *S. thermophilus* bacterial species resistant to infection by bacteriophage. However, in this case the disclosure is limited to two mutants of *S. thermophilus* bacterial chromosome and one mutant of prophage genome.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a modified strain of *S. thermophilus* bacterium, wherein said strain comprises any modification of its genomic DNA by any means in any ORF or at any gene resulting in disruption of expression of chorismate mutase gene in said bacterium (claims 1-2, 9-10, 18, 21-22, 25) or any modification in the in the prophage genome (claims 34-41). The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, making a modified strain of *S. thermophilus* bacterium by modifying the bacterial genome and prophage Sfi21 genome such that the mutant strain has the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Withdrawn-Claim Rejections - 35 USC § 102

Previous rejection of Claims 1-2, 7, 9-10, 18, 20, 22, 24, 28-31 under 35 U.S.C. 102(b) as being anticipated by Foley et al. ("A short noncoding viral DNA element showing characteristics of a replication origin confers bacteriophage resistance to *Streptococcus thermophilus*", *Virology*. 1998 Oct 25; 250(2): 377-87, see IDS) is withdrawn in view of Applicants amendment

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of claims and persuasive arguments. Foley et al. do not teach S. thermophilus strains resistant to attack by at least one bacteriophage, wherein said bacterium comprising a modification of bacterial chromosome sufficient to disrupt expression of a chorismate mutase A chain gene.

Withdrawn-Claim Rejections - 35 USC § 103

Previous rejection of Claims 3-4, 19, 21, 23, 25-27 under 35 U.S.C. 103(a) as being unpatentable over Foley et al. ("A short noncoding viral DNA element showing characteristics of a replication origin confers bacteriophage resistance to *Streptococcus thermophilus*", Virology. 1998 Oct 25; 250(2): 377-87, see IDS) as applied to claims 1-2 7, 9-10, 18, 20, 22, 24, 28-31 and further in view of Sturino et al. ("Construction of bacteriophage resistant strains of *Streptococcus thermophilus* by pGh9::ISS1 insertional mutagenesis", Journal of Dairy Science, vol. 81, no. Suppl. 1, 1998, p. 7, Joint Meeting of the American Society for Animal Science; Denver, Colorado, USA; July 28-31, 1998, see IDS) and the common knowledge in the art regarding the use of *S. thermophilus* for making milk products is withdrawn in view of claim amendments and persuasive arguments. The reason is discussed in withdrawn of 102 rejection above.

Conclusion

Claims 3-4, 19, 23, 26, 28-31 are objected to as dependent on rejected base and would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 1-2, 7, 9-10, 18, 20-22, 24-25, 27 and 34-41 are rejected.

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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